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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,192	07/02/2003	Ranajit Pal	00711CIP	4134

26418 7590 01/23/2008

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EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
01/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,192	PAL ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *8-14 and 16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 15 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 14, 2007, has been entered.

2. Claims 1-21 are pending. Claims 8-14 and 16-20 are withdrawn from consideration as nonelected inventions. Claims 1-7, 15 and 21 are considered in this Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **(New objection)** Claim 3 recites the limitation "cryptic epitopes" in Claim 1. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior rejection-maintained)** The rejection of Claim 15 under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement **is maintained** for the reason of record.

7. Applicant presents the same argument that Claim 15 is meant to be used to help develop a vaccine for HIV. Like a flu vaccine consisting of multiple substances which together inoculate people against multiple strains of influenza, the claimed vaccine could be a component of a HIV vaccine. Applicant asserts that the instant specification has shown that gp120-CD4 can elicit broadly neutralizing antibody responses; therefore, the specification has definitely enabled a person skilled in the art to incorporate the components, as set forth in Claim 15, into a vaccine.

8. Applicant's argument is considered, but again found not persuasive. Claim 15 claims a "full" vaccine, not a "partial" vaccine, therefore should be examined to its full scope. The previous Office actions have discussed in detail the challenges in HIV vaccine development. In view of the scope of the claim and state of the art, the instant specification is insufficient to convince one of ordinary skill in the art that the claimed vaccine can be effective for its intended use as a vaccine. In the present case, the specification has only disclosed that gp120-CD4 can generate antibody in goats, and the sera form immunized goats can neutralize laboratory-adapted HIV strains, such as HIV-IIIB and HIV-MN, in *in vitro* assays. However, as discussed in the previous Office actions, the art indicates that prior vaccines designed to produce neutralizing antibody responses against HIV infection have been largely ineffective for the intended purpose. Here, while goats can be used for generating antibodies, there is no evidence in the art indicating goats are an art-recognized animal model for HIV infection. The instant specification has not provided any working examples to show that the alleged gp120-CD4 can raise neutralizing

antibodies against primary HIV strains, or can elicit broadly neutralizing antibody responses against HIV infection in any art-recognized animal models. The specification has not provided any working examples to show that other alleged gp120-CD4 equivalents can induce neutralizing antibodies against HIV, either. Thus, the specification has not taught one of ordinary skill in the art that gp120-CD4, and its equivalent thereof, would be useful HIV vaccine against HIV infection *in vivo*. Therefore, the rejection is maintained.

9. (**Prior rejection- maintained-extended**) The rejection of Claims 1-7 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement **is maintained**, and now extended to Claims 15 and 21, for the reason of record.

10. Applicant asserts that to better clarify what is meant by an "equivalent thereof" in Claim 1, the claims has been amended to specify "an equivalent of any fragment of CD4 as used herein includes any molecule that mimics the conformation of any fragment of CD4 and which can bind to gpl20." Accordingly, Applicants assert that Claim 1 is now in allowable form.

11. Applicant's assertion is not convincing. Claim 1 as amended still lacks adequate written description because the specification has not defined what is "the conformation of any fragment of CD4". Since "the conformation of any fragment of CD4" and "cryptic epitopes" is not conventional in the art or known to one of ordinary skill in the art, one of ordinary skill in the art cannot envision what is "any molecule that mimics the confirmation of any fragment of CD4" and reveals "cryptic epitopes" without an adequate description by the specification. The instant claims do not have sufficient characteristic for written description, therefore, the rejection is

maintained.

12. **(Prior rejection- maintained- extended)** The rejection of Claims 1-7 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification commensurate in scope with these claims, **is maintained**, and is now extended to Claims 15 and 21, for the reason of record.

13. Applicant alleges that because the claims have been amended to specify "an equivalent thereof", the scope-of-enablement rejection should be withdrawn.

14. Applicant's argument is not convincing. Because of the lack of written description of the claimed "an equivalent" in the specification as discussed above, one of ordinary skill in the art would not know how to make alleged gp120-CD4 equivalents.

15. Moreover, it is noted that claims as amended are directed to a vaccine. The previous Office actions and this Office action have provide detail discussions indicating that the instant specification does not enable one of ordinary skill in the art to use the alleged immunogenic complex as a HIV vaccine. (See previous Office actions and Para 6-8 above).

16. As a result, the specification does not enable any person skilled in the art to which it pertains to make and use the invention commensurate in scope with these claims. The rejection is maintained.

Double Patenting

17. (**Prior rejection-maintained**) The rejection of Claims 1-7 on the ground of nonstatutory obviousness-type double patenting over Claim 1 of US 5,843,454, and Claim1 of US 5,518,723 **is maintained**, now extended to Claims 15 and 21.

18. Applicant acknowledges the rejection and does not wish to prematurely respond.

Claim Rejections – 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. (**New rejection necessitated by the amendment**) Claims 1-3, 5, 7, 15 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hart T. et al (Proc Natl Acad Sci U S A. 1991 Mar 15;88(6):2189-93; Cited as ref #12 in IDS 12/3/03).

21. Claims 1-3, 5, 7, 15 and 21 are directed to an immunogenic complex comprising gp120 covalently bonded to a fragment of CD4 or **an equivalent thereof**; wherein an equivalent of a fragment of CD4 is any molecule that mimics the conformation of any fragment of CD4 and which can bind to gpl20, wherein the said fragment of CD4 comprises the first and second domains of CD4.

22. Hart teaches a soluble CD4 (sT4) consisting of 1-369 amino acids of the CD4 molecule, and V1V2, DT molecule consisting of amino acids 1-183 of CD4 molecule (See Materials and Methods, p. 2189-2190). Hart teaches that sT4 and V1V2,DT molecules bind to gp120-gp41 via gp120, induce conformational change in gp120, which result in release of gp120 from gp41 (See

discussion, Para 1, p. 2192).

23. Since both sT4 and V1V2,DT molecules comprise the first and second domains of CD4, "mimics the conformation of any fragment of CD4, and can bind gp120", the sT4 and V1V2,DT molecules disclosed by Hart meet the limitations of the instant claims. Claims 1-3, 5, 7, 15 and 21 are anticipated by Hart.

Remarks

24. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Bo Peng/
January 22, 2008